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Management of OSTI-LLNL Electronic Data

Quality Implementing Procedure ID: OSTI-LLNL-QIP-SV.0, Rev.0, Mod.0

V. J. Barish, L. A. Gouveia

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QA: QA

MANAGEMENT OF OSTI-LLNL ELECTRONIC DATA

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1. PURPOSE

This Quality Implementing Procedure (QIP) describes the controls to be applied to the management of electronic data produced by scientific investigations for the Office of Science and Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) Project.

2. SCOPE

This procedure describes the overall responsibilities of the OSTI-LLNL Project to meet the requirements of the OSTI-LLNL Quality Assurance Plan (QAP) Supplement V, which implements Supplement V of the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P.

Supplement V of the QAP applies to the processes and controls for the management of data that either exist or are used in an electronic format. This includes electronic formatted data developed as an output of scientific investigation.

This QIP applies to quality assurance (QA) work activities performed for the OSTI-LLNL Project based on the following criteria:

- data are created and/or stored as electronic media
- data are manipulated from raw, or source data, to a reduced state
- file transfer protocol (FTP) is used to transmit or receive data
- data are transferred from a data logger or other device to a computer by modem
- data transfer to or from removable storage media (e.g. disks or tapes), by e-mail, or via the Ethernet
- conversion of files from one software format to another
- data are entered manually into a computer

The controls to be applied to data shall be implemented as described herein. This procedure contains the standard processes to be implemented; if the controls are to be further implemented in a Technical Implementing Procedure (TIP) or scientific notebook, the TIP or notebook will expand or elaborate on these processes.

Development of software including database applications or software that performs functions of analysis or calculation shall be controlled in accordance with OSTI-LLNL-QIP-SI.0, *Software Management*. The acquisition, development and use of preliminary data are an inherent part of scientific investigations and are controlled by OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*.

3. PROCEDURE

3.1 Accuracy, Completeness and Integrity of Data

The OSTI-LLNL **Scientific Staff** utilizes the Technical Data Management System (TDMS), or other OSTI approved databases, for storage, retrieval, and maintenance of electronic data that support analysis/technical/model reports. Data are transferred to and/or subsequently retrieved from the database, and incorporated within an analysis/technical/model report. The accuracy, completeness, and integrity of the data shall be verified by the originator of the technical product and through the review and checking requirements of the applicable QA procedures.

The first step of maintaining the integrity of the raw data in their preliminary form is the calibration of the equipment. Equipment failure or out of calibration conditions shall be addressed according to OSTI-LLNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*. The integrity of the preliminary data during transfer to local storage is covered in Section 3.2, and storage before submittal to TDMS is covered in Section 3.3.

In the course of the scientific investigation, **Scientific Staff** may manipulate raw field or laboratory data from the preliminary (source) data to a reduced (final) state. This step shall be documented in the scientific notebook entry, per OSTI-LLNL-QIP-SIII.0. The evaluation of the end results is performed by technical review, therefore no further controls outside the professional judgement of the investigator and the required reviews of the resulting data will be applied to data manipulation.

Electronic files may be converted from one software format to another. **Scientific Staff** shall include an entry in the scientific notebook indicating that a verification of the file conversion has been conducted. Scientific Staff shall indicate this verification by performing and documenting the following:

- visually compare the data (random or spot check) to confirm all data were converted;
- reconcile any differences to make the two identical;
- include in the scientific notebook entry
  - name, date, size, format, and location of original file
  - name, date, size, format and location of converted file

Data transfer and storage requirements listed in Sections 3.2 through 3.5 below necessitate that certain details concerning the data files are to be recorded in the scientific notebooks. Because the information to be recorded may be the same for many of the data files used, Attachment 1, OSTI-LLNL Supplement V Summary for Scientific Notebooks, is provided as a means to conveniently summarize the

information that applies to most data files. For data files that require different or additional information, the corresponding information shall be recorded in the appropriate scientific notebook entry. If Attachment 1 is not used, the same information shall be recorded in a scientific notebook or in documentation associated with the data and traceable to the data.

3.2 Data Transfer

OSTI-LLNL **Scientific Staff** commonly transfer preliminary data electronically employing the means listed in Sections 3.2.1 through 3.2.5, below. The following methods are used to ensure the accuracy and completeness of preliminary data transfer in an electronic system. The ethernet (see Section 3.2.3) is an electronic interconnection from one computer to another over dedicated lines. This is only a path of transfer, not a method.

3.2.1 Transfer of Data from Hard Copy to Computer Disk

The **Scientific Staff** entering data from hard copy to an electronic format or comparing data on hard copy to an electronic format shall include an entry in the scientific notebook indicating that verification of input from the hardcopy to the computer file holding the input data has been conducted. The **Scientific Staff** shall indicate this verification by performing the following:

- visually compare the hard copy data to the data as displayed on the monitor of the computer;
- reconcile any differences to make the two identical;
- include in the scientific notebook entry:
  - source of the data,
  - filename of the electronic input data, and
  - signature and date (or initials and date) for the scientific notebook entry per OSTI-LLNL-SIII.0 to indicate that the verification was performed.

3.2.2 FTP via the Internet

FTP via the internet has proven to be a dependable process for file transfer between two locations. On rare occasions, if a problem occurs during transfer, the file will not be available or will not open. In these cases, the end user knows the problem exists and is able to either request retransfer of the file or, if that is not possible, obtain the file by another means. Since FTP has been found to be dependable, there will be no further controls placed on the process.

3.2.3 Data Transfer from Data Logger to Computer Disk via Modem or Ethernet

File transfer from data logger to computer disk via modem or an ethernet has been found to be dependable. The type of information obtained by the data logger and transferred to the computer is well known to the investigator.

Frequent inspection and evaluation of the process being monitored by the data gathering equipment at the location where the information is gathered and knowledge of the data points expected gives the investigator confidence in the information transferred to the computer. Since spurious data are known to the investigator and evaluation of the end results is performed by technical review, no further controls outside the professional judgement of the investigator and the required reviews of the resulting data will be applied to this transfer method.

3.2.4 File Transfer from Disk to Disk

File transfer from disk to disk has proven to be dependable for the media used on the OSTI-LLNL Project (e.g., 3½" disk, Compact Disk (CD), zip disk, tape, hard drive, etc). Since the file information is known from the source medium by name and date, and usually size, the target medium will be checked visually for correct information in the log created during transfer. Also, the operating system on the computer being used has adequate process controls; any transfer problems are obvious to the user such that the transfer process will be performed with a caution or warning supplied by the system. The professional judgment of the user will be relied upon with no further controls placed on the process.

3.2.5 E-mail

This process shall be controlled by the user assuring that the sending and receiving e-mail applications are compatible in their encoding and decoding methods. File transfer through e-mail has been found to be dependable once the issue of compatible encoding/decoding has been resolved. A (one-time) trial file transfer between the subject computers shall be made employing the e-mail application(s) to be used later. The data shall be verified as correct by visual inspection, and the successful transfer shall be recorded (once) in a SN entry, including:

- the recipient,
- the filename,
- the date (indicated by scientific notebook entry date), and
- a statement to the effect that a correct transfer was accomplished.

Following this, the professional judgement of the user will be permitted with no further controls placed on the process.

No e-mail transfer of data to or from other OCRWM sites to OSTI-LLNL staff shall be employed in QA work activities. The data must be formally requested per OSTI-LLNL-QIP-SIII.5, *Scientific Analysis*, OSTI-LLNL-QIP-SIII.1, *Technical Reports* or OSTI-LLNL-QIP-SIII.2, *Model Reports*, and submitted in accordance with OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System.*

3.3 Data Storage and Maintenance

3.3.1 Data Storage Media

Typical storage media include computer hard drives, CDs, floppy disks, tape, zip drive, and file servers, all maintained in the protection of an indoor environment. These media are considered adequate for data storage for the typical retention time (e.g., up to one year) of the data before they are submitted to TDMS or the RC. The operating system on the computer, including servers, where the preliminary data are being stored has adequate process controls such that disk transfer problems are obvious to the user, reporting a caution or warning if the transfer to disk is incorrect. For CDs, floppy disks, tape, zip drives, etc., the media have been found to retain retrievable and accurate data for several years, much longer than the one-year retention time needed before submitting the data to TDMS.

Data supporting analysis/technical/model reports are submitted to the TDMS according to applicable requirements (e.g., OSTI-LLNL-QIP-SIII.5, OSTI-LLNL-QIP-SIII.1, OSTI-LLNL-QIP-SIII.3, etc.). Upon acceptance of the data, the TDMS maintains and stores the data according to applicable procedures.

3.3.2 Methods of Data Storage and Verification of Data Integrity

The method of data storage shall be determined by the **Scientific Staff** considering access controls, location of the data, storage medium, security, and protection of the storage medium from deleterious conditions such as extremes of temperature, humidity, etc., and the desired retention time of the data. The method of storage shall be recorded in a scientific notebook (Attachment 1 may be used for this purpose).

Following data storage, the integrity of the data shall be verified through the standard backup system provided by the LLNL/Energy & Environment Directorate (EED) for backing up computer systems. The LLNL/EED standard backup system has been found to be dependable and the associated utility software has inherent verification functions to ensure the integrity of the electronic data files. The copying utilities produce logs with error messages to the operator if an error occurs during storage of the data. The operating system performing the data transfer has the same warning messages from the system as mentioned above. Over many years, scientists have been able to recover files that were accidentally deleted or were damaged; backup copies of files are kept for more than one year so that recovery is available through the retention time of the data before they are sent to TDMS.

If the data files are stored on storage devices (e.g., zip drives) or media (e.g., CDs) that are not subject to the standard backup system for LLNL/EED, the Scientific Staff shall verify the integrity of such data (see data transfer verification in Section 3.2.4) and record that verification is successful in a scientific notebook entry subsequent to the transfer.

3.3.3 Maintenance of Data Files (Data Traceability and Retrievability)

To enable both traceability and retrievability, the **Scientific Staff** shall document the following information for data files supporting technical products:

- the source of data (e.g., computer ID, directory, instrument ID),
- the file identification (indicating full pathname for the file),
- file format, which may be indicated by a file extension such as *.txt for plain text, *.rtf for rich text, *.xls for Excel spreadsheet, *.jpg for JPEG (images), *.htm for HTML, etc. (where the "*" indicates the filename),
- origination date,
- the originator of the file, and
- the computer or other storage device or medium on which it resides.

This information shall be recorded or referenced in the scientific notebook. When data are determined to support a technical product, the data shall be transferred to the **Technical Data Coordinator** or designee to submit to the TDMS (see Section 3.6) in accordance with OSTI-LLNL-QIP-SIII.3.

For data files that support an analysis/technical/model report, scientific staff shall maintain traceability to the document they support. One reference can be made for a group of files that support the same technical product.

3.4 Equipment Access and Backup

Physical access to equipment used in maintaining preliminary electronic data (e.g., file servers, workstations, personal computers, instruments) is controlled by limited access to LLNL. Access to LLNL is controlled through the main gates, where posted security personnel screen employees and visitors. Moreover, the buildings/facilities are locked during off-hours. The **Scientific Staff** shall maintain a list in their scientific notebook of each person(s) with controlled access to the information system (Attachment 1).

Equipment maintaining OSTI-LLNL preliminary electronic data shall be backed up at a frequency determined by the LLNL Computer Administrator. Standard back-up systems shall be used whenever possible (see Section 3.3.2). Documentation of the method of backup shall be recorded in the scientific notebook (Attachment 1). If the nature of the data, the equipment or the scientific investigation requires additional back up requirements, these requirements will be listed in a TIP or scientific notebook.

3.4.1 Servers

Servers that have preliminary data shall have an established backup process. Backup media shall be labeled and stored with appropriate means depending on the media.

3.4.2 Workstations/Personal Computers

Computers with preliminary data shall have a backup process to ensure the data are protected from loss. Backup media shall be labeled and stored with appropriate means depending on the media.

3.4.3 Instruments

Data from instruments that have data shall be copied to a backup medium, which shall be appropriately labeled and stored. Any hard copy printouts shall be kept until the backup copies are appropriately verified (see data transfer verification methods in Section 3.2).

3.5 Security of Data

To ensure the security and integrity of the preliminary data, the **Scientific Staff** shall maintain a list in a scientific notebook (see Attachment 1) of each staff member or group of staff members with access to the electronic data and the computers on which it resides to ensure the security and integrity of the data. This list shall include:

- identification of the computers, including servers; for other storage devices or media, the location shall be specified,
- name of the individual(s) or group(s),
- type of access (read only, read/write), and how controlled,
- signature of the individual approving such access, and
- date of approval for access (see Attachment 1).

Servers and workstations/personal computers shall be accessible only to authorized personnel with proper authentication (e.g., a password).

3.6 Submittal of Data to the TDMS

3.6.1 Transfer of Data to the Technical Data Coordinator

Upon technical review of data supporting an analysis/technical/model report, the **Scientific Staff** shall transfer the data and associated records to the **Technical Data Coordinator,** in accordance with OSTI-LLNL-SIII.3.

3.6.2 Submittal of Data

The **Technical Data Coordinator** or designee shall transfer these data following one or more of the methods of Section 3.2, employing file compression, to the appropriate medium for submittal (e.g., CD, 3½" disk, tape, etc.). The file compression utilities have been found to be compatible with utilities employed by TDMS. After transfer to the medium, the **Technical Data Coordinator** or designee shall assure the original data identification as transferred is the same as those obtained from the sender or originator. The data

shall then be submitted to the TDMS by the **Technical Data Coordinator** in accordance with OSTI-LLNL-QIP-SIII.3.

4. RECORDS

The records listed below shall be collected and submitted to the RC in accordance with OSTI-LLNL-QIP-17.0, *Records Management,* as individual records or included in a records package, as specified.

4.1 QA Records

Attachment 1, if incorporated into a Scientific Notebook, as part of the scientific notebook records package.

4.2 Non-QA Long-Term Records

None

4.3 Non-QA Short-Term Records (Three Years or Less Retention)

None

5. RESPONSIBILITIES

Scientific Staff are responsible for meeting the requirements of this procedure regarding the transfer and storage of data and data files and their submission to the TDMS and RC.

The **Technical Data Coordinator** is responsible for preparing and submitting data to the TDMS in accordance with OSTI-LLNL-QIP-SIII.3.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

CD	Compact Disk
DOE	Department of Energy
EED	Energy & Environment Directorate
ESD	Earth Sciences Division
FTP	File Transfer Protocol
ID	Identification
LLNL	Lawrence Livermore National Laboratory
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science and Technology and International
QA	Quality Assurance

QAP	Quality Assurance Program
QARD	Quality Assurance Requirements and Description
QIP	Quality Implementing Procedure
RC	Records Center
TDMS	Technical Data Management System
TIP	Technical Implementing Procedure

6.2 Definitions

Data: As it pertains to Supplement III, information developed as a result of scientific investigation activities, including information extracted from reference sources, and performance assessment analysis (QARD).

Data File: An organized collection of related information, usually arranged in logical records that are stored together and treated as a unit; related numeric, textual, or graphic information that is organized in a strictly prescribed form or format.

Electronic Media: A form of media used to store, maintain, or transmit information that only a computer or other electronic device can read or process. Such media would include floppy disks, optical disks, hard drives, magnetic tape, etc.

Preliminary Data: Acquired or developed data that have not received a technical review that establishes and documents the technical validity of the data

Quality Implementing Procedure: Each QIP describes an aspect of the OSTI-LLNL implementation of QARD requirements.

Raw Data: Field or laboratory data that have not been converted to or do not occur as scientific or engineering terms as identified in the online Technical Data Parameter Dictionary. Raw data are not submitted to the TDMS.

Technical Implementing Procedure: Each TIP describes OSTI-LLNL technical and/or scientific tasks that are repetitive and standardized.

7. REFERENCES

DOE/RW-0333P, Quality Assurance Requirements and Description

OSTI-LLNL-QIP-6.1, *Document Review*

OSTI-LLNL-QIP-12.0, Control of Measuring and Test Equipment and Calibration Standards

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-SI.0, *Software Management*

OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*

OSTI-LLNL-QIP-SIII.1, *Technical Reports*

OSTI-LLNL-QIP-SIII.2, *Model Reports*

OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*

OSTI-LLNL-QIP-SIII.5, *Scientific Analyses*

8. ATTACHMENTS

Attachment 1 Supplement V Summary for Scientific Notebooks

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0:

Initial issue.

10. APPROVAL

Preparer: Leigh Gouveia — Date: 2/25/05

Technical Reviewer: Qinhong Hu QINHONG HU — Date: 2/25/05

QA Reviewer: VICTOR J. BARISH JR — Date: 2/25/05

Project Manager: DAVID B. McCALLEN — Date: 2/25/05

OSTI-LLNL Supplement V Summary

OSTI-LLNL DOCUMENT ID #: OSTI-LLNL-_____

The information below applies to each data file unless otherwise specified

- **Originator of electronic data files:** _____
- **Residing computer(s) (including servers) for electronic data files** (enter DOE property IDs)**:**
  _____
- **For electronic data file transfers:** *method(s) of transfer* are (check all that apply):
  ☐ Disk to disk ☐ FTP ☐ Ethernet/Internet ☐ E-mail ☐ Other: _____
  — The *method(s) for verifying the integrity of the data* in the notebook identified below apply to each transfer (check all that apply): ☐ Random checks of data content ☐ Visual checks of file format
  ☐ Checksums ☒ Other: _____

- **For information storage and maintenance of transferred or stored files:**
  — Media are protected from extremes of temperature, humidity, etc. by location onsite in an indoor environment. The type of medium is: ❑ Hard drive, including server files ❑ CD
  ☐ Floppy disk ☐ Tape ☐ Zip drive ☐ Other: _____
  — The *file format* is: ☐ plain text ☐ Excel spreadsheet ☐ rich text format
  ☐ Other: _____
  For Scientific Notebook entries, specify any particular formats (e.g., JPEG, HTML, etc.) for specific files in the entry where the file information is recorded. The format may be indicated by the file extension appended to the filename.
  — The *retention time* is up to one year, to ensure enough time to transmit data supporting technical products to the TDMS.

- **For electronic data file backups:**
  — The *standard backup system* provided by LLNL/EED for backing up computer systems is employed.
  — The *method for verifying the integrity of the data backup* is the inherent verification functions incorporated into the backup process by the standard backup system.

- **The security and access to electronic data files is as follows:**
  — Identify *type of access*: ☐ Read Only ☐ Read/Write
  — *Access is controlled* by password to computer system and/or off-hours locked building.
  — *Authorized Personnel* – attach list (For Scientific Notebook entries, individuals listed as *authorized personnel* on the Notebook Information page (including the PI) have access to the electronic data.)

Signature _____ Date _____
Originator